

TISSUE OPENING LOCATOR AND EVERTER AND METHODCross-Reference to Related Applications

This application is a continuation-in-part of U.S. Application Serial No. 09/092,282, filed June 5, 1998, which is a continuation-in-part of U.S. Application Serial No. 08/984,757, filed December 4, 1997, which is a continuation-in-part of U.S. Application Serial No. 08/943,369, filed October 3, 1997, which is a continuation-in-part of U.S. Application Serial No. 08/764,611, filed December 5, 1996, which claims the benefit of U.S. Provisional Application Serial No. 60/009,643 filed December 7, 1995.

Field of the Invention

The present invention relates to a system which assists in the locating of openings in tissue, including punctures, and facilitates the treatment, diagnosis or revision, of those areas. More specifically, in the case of closure of the opening, the invention relates to devices which aid in locating the opening, isolating the opening, and everting the edges of the opening, in order to facilitate closure of the opening.

Background of the Invention

In many medical procedures, there is a necessity to locate an opening in tissue so that some form of treatment, diagnosis or revision, can be applied to that opening. For example, in order to use transluminal balloon angioplasty an opening must be created in order to insert a balloon; this opening must be later located to be closed. Transluminal balloon angioplasty is used in the treatment of peripheral vascular disease to increase or restore blood flow through a significantly narrowed artery in a limb; it is also used in the treatment of blockage of the coronary arteries. In fact, coronary angioplasty has emerged as a major viable alternative to bypass surgery for revascularization of stenotic and occluded coronary arteries. Unlike bypass surgery, angioplasty does not require general anesthesia, opening of the chest wall, use of a heart-lung machine, or transfusion of blood. Angioplasty is not only less invasive and less traumatic to the patient, it is also less expensive because of the shorter hospital stay and shorter recovery time.

Transluminal balloon angioplasty is performed by first inserting a hollow needle through the skin and into the patient's femoral artery. A guidewire is advanced through the hollow needle and into the artery, then along the patient's vasculature toward the site of the blocked blood vessel or heart valve to be treated. X-ray imaging is used to help move the

05559700-081301
T05180-00452560

guidewire through the vascular system and into position just past the stenosis to be treated. A balloon catheter is then threaded over the guidewire and advanced until the deflated balloon is within the stenosis. The balloon is then repeatedly inflated to widen the narrowed blood vessel. After the procedure is complete, the catheter and guidewire are withdrawn from the blood vessels and the patient.

Angiography, which is used to detect diseases that alter the appearance of blood vessels, is performed in a similar manner. A hollow needle is first inserted through the skin and into the femoral artery, and a guidewire is then inserted through the needle and into the affected blood vessel. A catheter is then threaded over the guidewire and into the blood vessel to be examined, using x-ray imaging to guide the catheter to the desired position. Contrast medium is then injected, and a rapid sequence of x-ray pictures are taken so that blood flow along the affected vessel can be studied. Once complete, the catheter and guidewire are removed from the patient's body.

After the catheter and guidewire used during angioplasty or angiography are removed, the puncture wound in the femoral artery must be closed and the bleeding through the puncture site in the artery stopped. Currently, ice packs and/or pressure are applied to the artery for a period lasting up to several hours in an attempt to stop the bleeding. There exists, however, a significant chance that upon movement by the patient, the wound will reopen and begin bleeding again. Although efforts have been made to close the puncture wound using staples, clips, and sutures, they have been unsuccessful, largely due to the inability to clearly locate and visualize the puncture wound in the femoral artery.

Other wounds in the vasculature of a patient can also be difficult to locate and access. Thus, a device and method to facilitate the location of such wounds in the vasculature of a patient, such as femoral artery puncture wounds following transluminal balloon angioplasty and angiography, would be extremely beneficial. A device having the ability to aid in locating and isolating the puncture wound and facilitating the closure of the wound by everting the edges of the wound opening and then using staples, clips, sutures, plugs or adhesives would eliminate the prolonged bleeding currently associated with such wounds.

Summary of the Invention

09925700-061304

The preferred form of the invention facilitates the location of the tissue opening, e.g., an opening in a vessel. The purpose of such location is to allow for the performing of other medical procedures on the opening or surrounding tissue. These procedures include but are not limited to therapeutic (e.g., radiation, drug delivery, etc.), closure of the opening, or modification of the opening (e.g., enlarging the opening) procedures. Furthermore, the apparatus is capable of holding itself or another device on or near the opening by the apparatus's suction, which is preferably continuous but may be intermittent.

An apparatus for facilitating closure of an opening in a blood vessel, which includes a closure instrument having an elongated member defining a longitudinal axis with proximal and distal ends. The elongated member has a vacuum lumen extending at least a portion of the length thereof for conveying a vacuum and terminating in a vacuum port adjacent the distal end of the elongated member. The distal end of the elongated member is dimensioned to be positioned proximal a vessel opening in a blood vessel whereby vessel edge portions defining the vessel opening are at least drawn toward the vacuum port in response to a vacuum conveyed through the vacuum lumen. At least one surgical clip, preferably, two, is mounted adjacent the distal end of the elongated member and is adapted to be formed to an at least partially formed condition thereof. The one clip is positioned with respect to the vacuum port to engage the vessel edge portions drawn toward the vacuum port upon movement of the one clip to the formed condition thereof to generally approximate the vessel edge portions to at least partially close the vessel opening.

The apparatus may further include a clip forming member mounted to the elongated member and engageable with the one clip. The clip forming member is movable relative to the elongated member to move the one clip to the formed condition thereof. Preferably, first and second clip forming members are mounted to the elongated member in diametrically opposed relation.

In another preferred embodiment, an apparatus for facilitating closure of an opening in a blood vessel, includes an elongated member having a vacuum lumen extending at least a portion of the length thereof for conveying a vacuum and terminating in an axial vacuum port, a source of vacuum connectable to the elongated member in communication with the vacuum lumen whereby vacuum forces conveyed through the vacuum lumen and vacuum port cause vessel edge portions defining the vessel opening to

be at least partially drawn into the vacuum port such that the vessel edge portions assume a general everted condition, and a pair of surgical clips releasably mounted to the distal end of the elongated member adjacent the vacuum port and positioned to engage the vessel edge portions drawn into the vacuum port upon movement of the surgical clips to respective formed conditions thereof to thereby approximate the vessel edge portions to at least partially close the vessel opening. The apparatus may further include a manually actuable clip forming mechanism mounted to the elongated member. The clip forming mechanisms are movable to move the surgical clips to respective formed conditions thereof.

A method for locating a vessel opening in a blood vessel is also disclosed. The method includes the steps of applying a vacuum to the blood vessel adjacent the vessel opening such that the apparatus applying the vacuum first locates the area surrounding the vessel opening by drawing a mixture of blood and bodily fluid, then isolates the exact location of the vessel opening by being moved to the location where only blood is drawn. Once the location and isolation of a vessel opening is achieved, other medical procedures can be performed on the opening or its surrounding tissue. These medical procedures can be therapeutic (drug or radiation delivery) or closing or modifying (e.g. enlargement of vessel opening) in type. Also, once the vessel opening has been isolated, the further vacuum application everts vessel edge portions defining the vessel opening. Once eversion of the vessel edge portions occur, closing techniques can be used to close the opening.

Due to the use of a vacuum, contaminants and blood clots are cleaned off the puncture site allowing better healing of the wound. Also, re-entry is made easier and less scarring is produced.

Brief Description of the Drawings

FIGURE 1 is a side view of a portion of a human body, showing the site where the femoral artery is typically accessed and punctured during angioplasty or angiography.

FIGURE 2 is a perspective view of one embodiment of the wound closure device of the present invention.

FIGURE 3 is an exploded perspective view of the wound closure device of the present invention.

FIGURE 4 is a cross-sectional view of a portion of a human body, showing the femoral artery accessed via a hollow needle, and a guidewire having an inflatable balloon attached, inserted through the hollow needle and into the femoral artery.

5 FIGURE 5 is a side view of the distal end of a surgical clip applicator to be used in conjunction with the wound closure device of the present invention.

FIGURE 6 is a partial cross-sectional view of a portion of a human body, showing the femoral artery having a guidewire positioned therein, and a perspective view of the retractor of the present invention positioned over the guidewire, with its distal tip at the site of the puncture in the femoral artery.

10 FIGURE 7 is a side view of the retractor with its cap removed and the wings of the surgical clip applicator inserted into the grooves within the retractor.

FIGURE 8 is a cross-sectional view of the clip applicator and retractor taken along line 8-8 in FIGURE 7.

15 FIGURE 9 is a perspective view of an alternate embodiment of a femoral artery closure device in accordance with the present invention.

FIGURE 10 is an exploded perspective view of the alternate embodiment of the femoral artery closure device illustrated in FIGURE 9.

FIGURE 11 is a side view of the 2 halves of the retractor of FIGURES 9 and 10 separated slightly and having a dilator inserted therethrough.

20 FIGURE 12 is a cross-sectional view of the distal end of the retractor having a dilator and a guidewire inserted therethrough.

FIGURE 13 is a side view of the components of the femoral artery localization and closure assembly.

25 FIGURE 14 is a side view of the 2 halves of the retractor separated slightly and having a surgical clip applicator with an applicator guide and a guidewire inserted therethrough.

FIGURE 15 is a top view of the surgical clip applicator guide of the present invention.

30 FIGURE 16 is a side view of the clip applicator guide, having a guidewire inserted therethrough.

FIGURE 17 is an enlarged perspective view of a dilator having a removable double-sleeved balloon at its distal end.

FIGURE 18 is an enlarged perspective view of the dilator of FIGURE 17 with the sleeves of the balloon inflated.

FIGURE 19 is an enlarged perspective view of the dilator of FIGURE 18 having the retractor inserted between the sleeves of the balloon.

5 FIGURE 20 is an enlarged perspective view of the dilator and retractor of FIGURE 19 with the dilator removed, illustrating the tunnel formed by the retractor and the outer sleeve of the balloon.

FIGURE 21 is a perspective view of another alternate embodiment of a retractor in accordance with the present invention.

10 FIGURE 22 is an exploded perspective view of the alternate embodiment of the retractor illustrated in FIGURE 21.

FIGURE 23 is a perspective view of an alternate embodiment of a dilator having a double-sleeved balloon and a distal balloon mounted thereon in accordance with the present invention.

15 FIGURE 24 is a top view of another embodiment of the double-sleeved balloon, illustrating the I-shaped inner sleeve.

FIGURE 25 is a perspective view of the alternate embodiment of the dilator of FIGURE 23, showing the balloons inflated.

20 FIGURE 26 is a cross-sectional view of the dilator of the present invention, illustrating the various lumens in the dilator.

FIGURE 27 is a side view of the distal end of a surgical clip applicator with an indicator tube mounted thereon.

FIGURE 28 is a perspective view of an alternate embodiment of a retractor of the present invention, shown in a closed position.

25 FIGURE 29 is a perspective view of an alternate embodiment of a retractor of the present invention, shown in an open position.

FIGURE 30 is a side view of a dual-lumen indicator tube of the present invention, having a guidewire inserted through its central lumen.

30 FIGURE 31 is a side view of the dual-lumen indicator tube of the present invention, with the retractor mounted thereon.

FIGURE 32 is a perspective view of an apparatus for facilitating closure of an opening in a vascular organ illustrating the vascular closure instrument and a vacuum source connected to the closure instrument.

5 FIGURE 33 is an enlarged isolated view of the distal end of the closure instrument illustrating the pair of clips releasably mounted to the instrument.

FIGURE 34 is a cross-sectional view of the closure instrument in a non-actuated condition illustrating positioning of the distal end of the closure instrument proximal the vascular opening.

10 FIGURE 35 is an enlarged isolated view of the distal end of the closure instrument in the non-actuated condition proximal the vascular opening.

FIGURE 36 is a cross-sectional view of the closure instrument illustrating the closure instrument in an actuated condition.

15 FIGURE 37 is an enlarged isolated view of the distal end of the closure instrument in the actuated condition illustrating the surgical clips formed to close the vascular opening.

FIGURE 38 is a perspective view of an alternate embodiment of the vascular closure instrument of FIGURE 32.

FIGURE 39 is an enlarged isolated view of the distal end of the closure instrument of FIGURE 38.

20 FIGURE 40 is a cross-sectional view of a vessel opening and its surrounding, showing a tissue opening locator drawing both blood and other bodily fluid.

FIGURE 41 is a cross-sectional view of a vessel opening and its surrounding, showing a tissue opening locator solely drawing blood since the located has isolated the tissue opening.

25 FIGURE 42a is a front view of a tissue opening locator with a guidewire lumen located on its outside.

FIGURE 42b is a front view of a tissue opening locator with a guidewire lumen located inside.

30 FIGURE 43 is a cross-sectional view of a vessel opening and its surrounding, showing a tissue opening locator with medical procedure deliver devices located both inside and outside the tissue opening locator.

FIGURE 44 is a cross-sectional view of a vessel opening and its surrounding area, showing a guidewire that enters the vessel opening.

FIGURE 45 is a cross-sectional view of a vessel opening and its surrounding area, showing a tissue opening locator locate the vessel opening.

5 FIGURE 46 is a cross-sectional view of a vessel opening and its surrounding area, showing a tissue opening locator isolate a vessel opening and evert the vessel opening edges.

FIGURE 47 is cross-sectional view of a vessel opening and its surrounding, showing a tissue opening locator an attached general closure device.

10 Figure 48 is a top view of an alternate embodiment of a retractor having features of the present invention, shown in an open position.

Figure 49 is a top view of the retractor of Figure 48, shown in a closed position.

Figure 50 is a bottom perspective view of the retractor of Figure 48.

Detailed Description of the Preferred Embodiment Introduction

15 Although the description which follows details the location, eversion, and closure of a puncture wound in a femoral artery, the present invention is not intended to be limited to use only with the femoral artery. Rather, the description which follows is exemplary and preferred only, and those of skill in the art can readily modify the apparatus and method described below to use with other types of tissue openings.

20 Referring first to FIGURE 1, there is shown a side view of a portion of a human body, showing a site 5 where a femoral artery 10 is typically accessed and punctured during angioplasty or angiography. During these procedures, a hollow needle 15 is first inserted through the skin and into the femoral artery 10. A guidewire 20 is then inserted through the proximal end of the hollow needle 15 and into the artery 10, as illustrated in
25 FIGURE 4, and the needle 15 is withdrawn from the patient. The guidewire 20 is advanced through the patient's vasculature, often using x-ray imaging as an aid in directing the guidewire 20 to the desired location.

30 Once the guidewire 20 is in the desired location, a catheter is used. The proximal end of the guidewire 21 is inserted into the distal end of the catheter, and the catheter is threaded over the guidewire 20 and advanced to the desired location. In the case of angioplasty, the catheter has an inflatable balloon attached at its distal end. Once in position within the stenosis, the balloon is repeatedly inflated and deflated to widen the

narrowed blood vessel. In the case of angiography, a catheter is threaded over the guidewire 20 as just described and into the blood vessel to be examined. Contrast medium is then injected, and a rapid sequence of x-ray pictures are taken so that blood flow along the affected vessel can be studied.

5 After either of these procedures is completed, the catheter and guidewire 20 are withdrawn from the blood vessel and the patient. The puncture wound 25 in the femoral artery 10 caused by the insertion of the hollow needle 15, guidewire 20 and catheter must be closed and the bleeding through the puncture site 25 in the artery 10 stopped.

Construction of the Retractor

10 In order to facilitate the closure of the wound 25 in the femoral artery 10, a retractor 30 is employed. The retractor 30, illustrated in FIGURES 2 and 3, comprises a body portion 35 and a cap 40. The body 35 of the retractor 30 has a narrow, tapered distal end 37, and a broader circular proximal end 41. The device 30 has two handles 43, 45 located on its body 35, one on each half 35a, 35b. The handles 43, 45 are positioned
15 approximately one-third of the way from the proximal end of the retractor 41, and extend laterally from the body of the retractor 35. These handles 43, 45 assist the user in handling the device 30. The retractor 30 also comprises a circular cap 40 at its proximal end 41, having a hole 47 therethrough. This hole 47 extends into a channel 50 which runs the entire length of the device 30.

20 As illustrated in FIGURE 3, the cap 40 and body 35 of the retractor 30 comprise three separable pieces: the cap portion 40 and the two halves of the body portion 35a, 35b. The removable cap 40 is internally threaded 55. The proximal end 39 of the two halves of the body 35a, 35b are externally threaded 60, and are adapted to removably receive the cap 40. Each half of the body of the retractor 35a, 35b has a semi-circular groove 65 on its flat
25 internal surface 67. When the cap 40 is securely screwed onto the two halves of the body 35a, 35b as illustrated in FIGURE 2, the three pieces are joined together, and the semi-circular grooves 65 form a channel 50 running through the interior of the device 30, which starts at the hole in the cap 47 at the proximal end 41 and continues through the body 35, ending at a small hole 49 in the distal end of the retractor 37 where the two halves of the
30 body 35a, 35b come together. When the cap 40 is unscrewed from the body 35, the two halves of the body 35a, 35b may be moved apart from one another, as illustrated in FIGURE 3.

Alternate Embodiment of the Retractor

Another preferred embodiment of the invention is illustrated in FIGURES 9-10. In this embodiment, the retractor 100 includes a retraction mechanism whereby the two halves 102a, 102b of the retractor body 102 can be moved apart from one another a desired distance, while maintaining their alignment. The retractor again comprises a body portion 102, and an annular cap 104. The two halves 102a, 102b of the body are initially held together by the internally threaded 105 cap 104. This cap 104 is screwed on and off the externally threaded halves 102a, 102b of the retractor body. The outer surface of the cap 106 can be textured to ease hand tightening and loosening of the cap 106. As illustrated in FIGURE 10, each half 102a, 102b of the retractor body again has a semicircular groove 126 running longitudinally down the center of its flat internal surface 128. When the cap 104 is securely screwed onto the two halves 102a, 102b of the retractor body, such that the internal surfaces 128 abut one another, the semicircular grooves 126 form a channel 108. The cap 104 is open on both ends and through its center to permit access to the channel 108.

The retractor 100, as illustrated in FIGURES 9-10, further comprises a collar 110 located on the retractor body 102 just distal to the externally threaded proximal end 103; a pin assembly 116, comprising two parallel pins 116a, 116b attached at one end to a perpendicular handle 116c; and two set screws 120a, 120b. As illustrated in FIGURE 10, the pins 116a, 116b traverse guide passages 118a, 118b bored through the collar region 110b of one half 102b of the retractor body and are insertable within holes 124a, 124b in the collar region 110a of the other half 102a of the retractor body, such that one half 102b of the retractor body can slide apart from the other half 102a on the pins 116a, 116b. The collar 110b includes internally threaded holes 122a, 122b adapted to receive externally threaded set screws 120a, 120b. The set screw holes 122a, 122b enter the collar region 110a at right angles to the pin guide passages 118a, 118b, such that when the set screws 120a, 120b are advanced, they tighten upon the pins 116a, 116b and thus, fix the distance between the two halves 102a, 102b of the retractor body.

Second Alternate Embodiment of the Retractor

Yet another embodiment of the retractor of the present invention is illustrated in FIGURES 21 and 22. The retractor 200 comprises a body portion 202 having a distal end 204, and a broader, collar portion 206 at its proximal end 205. Like the embodiment

described above, this retractor 200 is formed in two halves 202a, 202b and preferably has a tapered distal end 204. Each half of the body of the retractor 202a, 202b, has a semi-circular groove 208 on its flat internal surface 209. When the two halves 202a, 202b are joined together, the semi-circular grooves 208 form a channel 210 running through the interior of the device 200, extending from the proximal end 205 to the distal end 204.

The collar 206 of the device 200 includes a pin assembly 212 comprising two parallel pins 212a, 212b attached at one end to a handle 212c, and two set screws 214a, 214b. As illustrated in FIGURE 22, the pins 212a, 212b traverse guide passages 216a, 216b bored through the collar region 206 of one half of the retractor body 202b, and are insertable within holes 218a, 218b in the collar region 206 of the other half of the retractor body 202a, such that one half of the retractor body 202b can slide apart from the other half 202a on the pins 212a, 212b. The collar 206 also includes internally threaded holes 220a, 220b adapted to receive externally threaded set screws 214a, 214b. The set screw holes 220a, 220b enter the collar region 206 at right angles to the pin guide passages 216a, 216b such that when the set screws 214a, 214b are advanced, they tighten upon the pins 212a, 212b and thus, fix the distance between the two halves of the retractor body 202a, 202b.

Third Alternate Embodiment of the Retractor

Still another embodiment of the retractor of the present invention is illustrated in FIGURES 28 and 29. The retractor 300 comprises a distal body portion 302, and a proximal handle portion 304. The distal body portion 302 of the retractor 300 is formed in two portions or halves 302a, 302b. At the distal end 306 of the body portion 302, a retracting portion 308 extends away from, and at an angle to the body portion 302. Preferably, the retracting portion 308 extends substantially perpendicular to the body portion 302. The retracting portion 308 is also formed in two separable portions or halves 308a, 308b. Each of these portions 308a, 308b can be semi-circular in shape, or have a semi-circular groove 312 in its flat, internal surface (FIGURE 29). The external surfaces are preferably rounded, and tapered toward the distal end 310. When the two portions 308a, 308b are brought together such that the two portions abut one another, as seen in FIGURE 28, a channel 314 is formed through the interior of the retracting portion 308 of the retractor 300.

Handles 316a, 316b are located at the proximal end 304 of the retractor 300. The handles 316a, 316b are preferably elongate and of a dimension sufficient to permit

manipulation by hand. The handles 316a, 316b are securely connected to the body portion 302 of the retractor 300. The handles 316a, 316b are used to control the movement of the retracting portion 308 of the retractor 300.

FIGURES 28 and 29 also illustrate a loop 320 extending from one of the handles 316a in the direction of the other handle 316b. The other handle 316b has a screw 322 inserted therethrough. The loop 320 surrounds the screw 322, such that when the screw 322 is tightened, the loop 320 is held securely between the screw 322 and the underlying surface. This mechanism acts to control the distance between the handles 316a, 316b thereby controlling the distance between the two halves of the retracting portion 308a, 308b. The handles 316a, 316b, and the corresponding retracting portions 308a, 308b may be locked into any position by sliding the loop 320 along the screw 322, then tightening the screw 322 to securely fix the loop 320 in the desired position. Of course, other locking mechanisms well known to those of skill in the art may also be used to control the positioning of the retractor 300.

15 Fourth Alternate Embodiment of the Retractor

Yet another embodiment of the retractor of the present invention is illustrated in FIGURES 48-50. The retractor 600 comprises a distal body portion 602 and a proximal handle portion 604. The distal body portion 602 of the retractor 600 is formed in two portions or halves 602a, 602b. At the distal end 606 of the body portion 602, a retracting portion 608 extends away from, and at an angle to, the body portion 602. Preferably, the retracting portion 608 extends substantially perpendicular to the body portion 602. The retracting portion 608 is also formed in two separable portions or halves 608a, 608b. Each of these portions 608a, 608b preferably has a semi-circular groove 612 in its internal surface. The external surfaces are preferably rounded, and tapered toward the distal end 610. When the two portions 608a, 608b are brought together such that the two portions abut one another, as seen in FIGURE 49, a channel 614 is formed through the interior of the retracting portion 608 of the retractor 600.

Handles 616a, 616b are located at the proximal end 604 of the retractor 600. The handles 616a, 616b are preferably elongate and of a dimension sufficient to permit manipulation by hand. Each handle 616a, 616b is preferably formed as a unitary piece with a corresponding body portion 602a, 602b, respectively. The handles 616a, 616b are used to control the movement of the retracting portion 608 of the retractor 600. A hinge

618 operating between the handle/body pairs 616a/602a, 616b/602b is adapted so that when the handles 616a, 616b are moved away from each other, the body halves 602a, 602b are moved toward each other.

FIGURES 48-50 also show a stop bar 620 extending from one of the handles 616b and through a cavity formed in the other handle 616a. The stop bar 620 is preferably curved along an arc having the hinge 618 as a center of curvature. Teeth 622 are formed along a surface of the arcuate stop bar 620. A ratcheting release member 624 comprising an arm 626 and a head portion 628 extends through and from the handle half 616a through which the stop member 620 passes. The release member 624 is pivotably connected to the handle half 616a by a pivot pin 630 extending through the head 628. The head 628 comprises a stop 634, which is adapted to engage the teeth 622 of the stop bar 620, and a lobe 636 which extends through the handle 616a. A bar spring 638 connected to the handle half 616a contacts the lobe 636 and exerts a force F thereon. The force F exerted by the bar spring 638 on the lobe 636 biases the head stop 634 into engagement with the stop bar teeth 622. The arm 626 of the release member 624 is preferably arcuate and is adapted to be easily manipulated by a hand also grasping the handles 616a, 616b. Pulling the arm 626 toward the handle 616a overcomes the biasing force F and moves the head stop 634 out of engagement with the stop bar teeth 622.

A spring 640 is attached to and operates between the handles 616a, 616b. Preferably, the spring 640 is adapted to exert force F' on the handles 616a, 616b, biasing the handles apart from each other. Thus, the spring 640 biases the retracting portion halves 602a, 602b towards each other. Engagement of the release member stop 634 in the stop bar teeth 622 is adapted to prevent movement of the handles apart from each other. However, the release member stop 634 is also adapted so that when the handles 616a, 616b are squeezed toward each other, opening the retraction portion halves 602a, 602b, the head stop 634 "ratchets" over the teeth 622. Thus, movement of the handle halves 616a, 616b toward each other is accommodated by the stop 634, but movement of the handle halves 616a, 616b away from each other is prevented by the stop 634 when it is engaged with the stop bar teeth 622. Thus, a clinician using the retractor 600 can open the retractor halves 602a, 602b to a precise point by simply squeezing the handle halves 616a, 616b together. The stop 634 and stop bar 620 prevent the retractor halves 602a, 602b from closing again once the desired open position is reached. When the clinician desires to

close the retractor 600, the clinician need only manipulate the release member arm 626, thus disengaging the stop 634 from the stop bar teeth 622. The hinge 640 then urges the handle halves 616a, 616b away from each other and the retractor halves 602, 602b toward each other into the closed position.

5 The retractors of the present invention are preferably formed of one of many strong, biocompatible engineering polymers. Plastics such as polypropylene, polyethylene, or polyterephthalate, are preferred. Elastomers such as silastics or silicones can also be used. Most preferably, metals such stainless or surgical steel, or titanium, are used to form the retractor.

10 Construction of the Dilator

As illustrated in FIGURES 11-13, the retractor 100 is preferably used in conjunction with a dilator 150. As is known to those of ordinary skill in the art, the hollow dilator 150 preferably includes a standard male connector 149, such as a Luer connector, at its proximal end and is narrowly tapered at its distal end 151. The inside diameter of the dilator channel 160 is large enough to accommodate a guidewire 144, so that the dilator 150 can be fed along the guidewire 144 and into the lumen of the femoral artery. Dilators are commonly used in procedures such as angioplasty and angiography to enlarge the puncture site and provide improved access to the femoral artery.

15 In one embodiment of the present invention, the dilator is preferably notched 152 near its distal end 151 around its entire circumference. This notch 152 provides a seat for the tapered distal tips of the two halves 102a, 102b of the retractor body, such that when the retractor 100 is closed upon the dilator 150, the sharp distal tip of the retractor body 112 is buried in the notch 152 of the dilator. This forms a smooth transition between the dilator 150 and retractor 100 (FIGURE 12). As will be explained more fully below, when the guidewire 144 is inserted through the dilator 150 and the dilator 150 is then inserted through the retractor 100, (FIGURES 12-13), the dilator 150 lies securely within the interior circular channel 108 (FIGURE 9) running the length of the retractor body 102.

20 The dilator 150 also preferably includes at least one indicator hole 154. The dilator 150 illustrated in FIGURES 11-13 includes two indicator holes 154 directly opposed to one another, located a few millimeters distal to the notch 152; the distance X between the holes 154 and the notch 152 is preferably only slightly larger than the thickness of the wall of the femoral artery.

Alternatively, a transducer-tipped pressure monitoring catheter, mounted to the outside of the dilator 150, may be used in conjunction with the dilator 150 and indicator holes 154. Use of the indicator holes 154 and pressure sensor will be described in detail below.

5 Dilator/Retractor Assembly

Another embodiment of the present invention comprises an entire femoral artery localization and closure assembly illustrated in FIGURE 13. The guidewire 144 which emerges from the original puncture wound is fed through the dilator 150, and then the dilator 150 is inserted through the retractor 100. The retractor 100 is advanced along the dilator 150 until the distal tips of the retractor 112 stop within the notch 152 in the dilator 150. Preferably, the male fitting 149 on the proximal end of the dilator 150 is connected to one port of a commercially available 3-way Y-connector 156. A syringe 158 or other means of applying negative pressure is connected to one of the other ports on the Y-connector 156 and the proximal end of the guidewire 144 exits the Y-connector 156 via the remaining port. The Y-connector 156 therefore acts as a seal at the proximal ends of dilator 150 and guidewire 144.

15 Alternate Embodiments of the Dilator

In another embodiment of the invention, a modified dilator 150 is used. As illustrated in FIGURE 17, a double-sleeved balloon 170 is removably attached to the dilator 150 near its distal end 151, proximal to a single indicator hole 154. Preferably, the balloon 170 is placed a distance from the indicator hole 154 which is approximately the width of the arterial wall, e.g., about 1.5 mm. The inflatable, double-sleeved balloon 170 is angled at its distal end 172 to allow the balloon to better fit the femoral artery 10. The balloon 170 includes inflation means which allow the balloon to be inflated and deflated from the proximal end of the dilator 150. Use of the double-sleeved balloon 170 will be described in detail below.

In yet another embodiment, illustrated in FIGURES 23-25, the dilator 220 has both a double-sleeved balloon 222 and a second inflatable balloon 224 mounted on its distal end 226. The double-sleeved balloon 222 is removably attached to the dilator 220 near its distal end 226, proximal to the single indicator hole 228. The second inflatable balloon 224 is mounted on the dilator 220 just distal to the indicator hole 228. When inflated, this second balloon 224 helps anchor the dilator 220 in place in the femoral artery 10,

preventing the dilator 220 from being pulled out of the artery 10 during the procedure. Thus, the distal, second balloon 224 is positioned together with the indicator hole 228, within the artery 10, while the double-sleeved balloon 222, proximal to the indicator hole 228, remains outside of the artery 10 as illustrated in FIGURE 25. The balloons 222, 224 assist in the proper positioning of the dilator 220, and help anchor the dilator 220 once it is properly positioned, as will be explained in detail below.

The inner sleeve 230 of the double-sleeved balloon 222 is preferably shaped to facilitate the insertion of the retractor 200 between the two sleeves 229, 230, as will be described in more detail below. As illustrated in FIGURE 24, the inner sleeve 230 can be in the shape of an "I", thus providing additional space between the inner surface of the outer sleeve 229, and the outer surface of the inner sleeve 230. This allows the two halves of the retractor body 202a, 202b to be inserted between the two sleeves 229, 230 more easily. The two sleeves of the balloon 229,230 can be shaped in any form that would help facilitate insertion of the retractor 200.

The dilator 220 having both a double-sleeved balloon 222 and a second, distal balloon 224, is further illustrated in FIGURE 26. As can be seen from the drawing, the dilator 220 has 4 different lumens 232, 234, 236, 238 extending from the proximal end of the dilator 225 to the distal end of the dilator 226. A guidewire 240 is inserted through one of the lumens 236. Another lumen 232 is used to inflate the double- sleeved balloon 222, while a third lumen 238 is used to inflate the second balloon 224 at the distal end of the dilator 226. The fourth lumen 234 is used to aspirate blood through the indicator hole 228 at the distal end of the dilator 226. Syringes are preferably used to provide the aspiration and inflation pressure through these lumens 232, 234, 236, 238. The proximal end of the dilator 225 is preferably adapted to allow for fluid communication between the syringes and the various lumens 232, 234, 236, 238 in the dilator. Of course, other means of aspirating blood and inflating the balloons may also be used, and connectors specifically adapted for these devices can be attached at the proximal end of the dilator 225 to accommodate the means chosen.

Dual Lumen Catheter

In yet another embodiment of the invention, a dual-lumen catheter is used to locate the exact site of the puncture wound. As illustrated in FIGURES 30 and 31, the catheter 340 has an inner lumen 342 which extends from the proximal end of the catheter 344 all

the way to the distal end of the catheter 346. This inner lumen 342 is adapted to receive an inner catheter 360 or guidewire 350, as will be explained in more detail below.

5 The outer lumen of the dual-lumen catheter 340 surrounds the inner lumen 342, and also extends from the proximal end of the catheter 344 to the distal end 346. Near the distal end of the catheter 346, at least one indicator hole 352 is positioned in the outer wall of the catheter 340. The indicator hole 352 provides fluid communication between the area outside of the catheter 340 and the outer lumen. The outer surface of the catheter 354 surrounding the indicator hole 352 is preferably raised, acting as a stop. Preferably, the distance between the indicator hole 352 and the proximal end of the raised surface of the retractor 354, is approximately the same as the thickness of the wall of the femoral artery. As will be explained below, the retractor 300 is first mounted on the distal end of the catheter, and positioned such that the distal tip of the retracting portion 310 stops just proximal to the raised surface 354, about 0.5 mm proximal to the indicator hole 352. This assures that the distal tip of the retracting portion 310 will be properly positioned inside the patient's body at the site of the wound in the artery.

15 At the proximal end of the catheter 344, the proximal end 358 of the outer lumen is preferably joined to a connector 364, such as a Luer-type connector, which is adapted to receive a syringe 360 or other source of negative pressure, as will be explained in more detail below.

20 The Surgical Clip Applicator

The retractor of the present invention is used to facilitate closure of wounds to the vasculature of a patient using surgical clips, staples, or sutures. One aspect of the present invention therefore includes the use of a surgical clip applicator 70. A surgical clip applicator 70 for use with the retractor 30 of the present invention is illustrated in FIGURE 5. As shown in this figure, the distal end of the clip applicator 75 is fitted with two triangular protrusions or wings 77a, 77b that extend laterally from the sides of the distal end of the clip applicator 75. These wings 77a, 77b are configured to fit within the grooves 65 located on the interior surface of the two halves 35a, 35b of the body of the retractor 30, as is best seen in FIGURE 8. With the wings 77a, 77b of the clip applicator 70 in the grooves 65 in the two halves of the body of the retractor 35a, 35b, the clip applicator 70 is guided into proper position within the patient's body, as will be discussed in more detail below. In addition, the surgical clip applicator 70 preferably has a guide 80

attached to its distal end 75. The guide 80 preferably extends laterally from the side of the clip applicator 70, and is open at its proximal and distal ends such that a guidewire 20 may be threaded therethrough. This guide 80 is used in combination with the guidewire 20 to accurately guide the clip applicator 70 to the site of the vascular puncture 25, as will be described below.

The surgical clip applicator 70 preferably also has a stop 85 located proximal of the distal end 75, at the point where the proximal ends of the wings of the applicator 77a, 77b end. As will be explained, the stop 85 also aids in the proper positioning of the clip applicator 70 at the site of the vascular puncture 25, and prevents the clip applicator 70 from being inserted too far into the patient's body.

Alternate Surgical Clip Applicator Assembly

Referring now to FIGURES 14-16, there is illustrated an alternate embodiment of a surgical clip applicator assembly 130. The clip applicator assembly 130 incorporates a standard commercially available surgical clip applicator 132. In accordance with the present invention, the applicator is modified to include a guide assembly 134 reversibly fastened near its distal end. The guide assembly comprises a winged guide plate 138 which is reversibly secured to a body 140. In the embodiment illustrated in FIGURES 14-16, allen screws 142 are used to attach the guide plate 138 but other well known means of attachment can also be used. The distal end of the surgical clip applicator 132 slides within the channel 148 (FIGURE 15) formed when the winged guide plate 138 is fastened to the guide body 140.

Attached to the guide body 140 is a guidetube 136 which is adapted to accept the guidewire 144. A preferred embodiment of said guidetube 136 includes a mechanism to close the guidetube 136 once the guidewire 144 has entered. Such a mechanism may involve a second partially open tube which fits within said guidetube 136. This second tube can be rotated within the guidetube 136 to open the guidetube 136 when the openings in both tubes are aligned or close the guidetube 136 when the openings of the tubes are offset. To facilitate the opening and closing, the inner tube preferably includes a handle that passes through a slot in the outer guidetube 136. This mechanism can be spring-loaded like the closures commonly used on pieces of jewelry.

The surgical clip applicator guide assembly 134, together with the retractor 100 and the guidewire 144, is designed to accurately guide the clip applicator 132 to the site of

the femoral artery puncture as detailed below. As explained above, the lateral edges of the winged guide plate 138 are configured to fit within the groove 126 (FIGURE 10) located on the interior surface of each half of the retractor body 102a, 102b. The surgical clip applicator 132 is guided between the retracted halves of the retractor body 102a, 102b following the guidewire 144 which passes through the guidetube 136 at the distal most end of the surgical clip applicator 132.

Second Alternate Surgical Clip Applicator Assembly

An alternate embodiment of the surgical clip applicator assembly 250 is illustrated in FIGURE 27. Again, the clip applicator assembly 250 incorporates a standard commercially available surgical clip applicator 252. The applicator 252 is modified to include a guide assembly 254 reversibly fastened near its distal end 256. The guide assembly 254 is adapted to receive an indicator tube 260. The indicator tube 260 is a hollow tube having an indicator hole 264 near its distal end 262. The indicator tube 260 is adapted to receive a guidewire 240 therethrough, and to be connected to a source of negative pressure at its proximal end. This source of negative pressure, such as a syringe, is used to provide aspiration through the indicator hole 264. When properly positioned on the clip applicator 252, the distal end of the indicator tube 262 and the indicator hole 264 extend past the distal end of the clip applicator 256. Preferably, the distance between the indicator hole 264 and the distal tip of the clip applicator 256 is approximately equal to the width of the arterial wall, e.g., about 1.5 mm.

Methods of Use

Referring first to FIGURES 4-8, a first method of use of the retractor 30 in conjunction with a surgical clip applicator 70 to close a wound 25 in the femoral artery 10 will now be described. As noted above, during angioplasty or angiography, the femoral artery 10 is first punctured with a hollow needle 15 and a guidewire 20 is inserted therethrough (FIGURE 4). A proximal portion of the guidewire 21 remains outside the patient's body. After the distal end of the guidewire 23 is in position within the femoral artery 10, the hollow needle 15 is removed. A catheter (not shown) is then threaded over the guidewire 20, and inserted into the patient's body.

In a preferred embodiment, a specially designed guidewire 20 having an inflatable balloon 24 located near its distal end 23 is used for the diagnostic or therapeutic procedure.

The guidewire 20 is threaded through the hollow needle 15 and into the patient's vasculature. Alternatively, such as for balloon angioplasty procedures, a standard guidewire well known to those of skill in the art can be used in conjunction with a balloon catheter. The balloon on the distal end of the catheter can be used in place of the balloon 24 located on the guidewire 20.

Following completion of the therapeutic or diagnostic procedure, the catheter used during the procedure is removed. The guidewire 20 remains in place in the patient's vasculature. (Note that when a balloon catheter is used in place of a guidewire having a balloon on its distal end, the catheter is left inside the patient, and use of its balloon is identical to the use of the balloon 24 on the guidewire 20 described below). When the physician desires to close the wound 25 in the femoral artery 10, he or she first withdraws the guidewire 20 and/or catheter through the patient's vasculature using the portion of the guidewire 20 and/or catheter that remains outside the patient's body 21, until the distal end 23 of the guidewire 20 and/or catheter is within the femoral artery 10 close to the femoral artery puncture site 25. The balloon 24 on the distal end 23 of the guidewire 20 or catheter is then inflated, and the guidewire 20 or catheter is withdrawn further until the physician feels some resistance. This will indicate that the balloon 24 is inside the femoral artery 10 and at the site of the puncture wound 25. The physician then threads the proximal end of the guidewire 21 into the hole 49 located at the distal end 37 of the fully assembled retractor 30 (FIGURES 2, 3 and 6). The guidewire 20 is threaded through the channel 50 formed in the body of the retractor 35, until the proximal end of the guidewire 21 emerges through the hole 47 in the cap 40 at the proximal end of the retractor 41 (FIGURE 6). The retractor 30 is then slowly advanced along the guidewire 20 and into the patient's body, until resistance is felt. This resistance indicates that the distal tip of the retractor 37 is contacting the inflated balloon 24 in the femoral artery 10. The distal tip of the retractor 37 therefore will be properly located at the site of the puncture in the femoral artery 25, as is shown in FIGURE 6.

In a preferred embodiment, the guidewire 20 used in conjunction with the femoral artery closure retractor 30 has a marking 27 on it which also helps to indicate when the retractor 30 has been properly positioned (FIGURE 6). This marking 27 preferably consists of a tiny bead or colored line on the guidewire 20. The marking on the guidewire 27 is placed proximal of the proximal end of the balloon 26. The length of the retractor 30

is measured, and the marking 27 is made at least that same length in a proximal direction on the guidewire 20, measured from the proximal end of the balloon 26. Thus, when the retractor 30 is advanced over the guidewire 20 and resistance is felt, the physician checks to see if the marking on the guidewire 27 has emerged through the proximal end of the retractor 41, as is illustrated in FIGURE 6. If the marking 27 is not yet visible, the physician must advance the retractor 30 further to ensure that it contacts the femoral artery puncture site 25.

Once the retractor 30 is properly positioned within the patient's body, the surgical clip applicator 70 or other method of closing the puncture wound 25 is used. The cap 40 on the retractor 30 is first removed from the body by unscrewing (FIGURE 3). The proximal end of the guidewire 21 emerging from the proximal end of the retractor 41 is threaded through the guide 80 located on the outer surface of the applicator 70, as illustrated in FIGURE 7. The wings on the surgical clip applicator 77a, 77b are inserted into the hole 90 formed at the proximal end of the body of the retractor 39, by lining up the wings 77a, 77b on the applicator 30 with the grooves 65 located on the inner surface 67 of the retractor body halves 35a, 35b (FIGURES 7 and 8). The wings on the clip applicator 77a, 77b are sized to fit within the grooves 65 of the retractor 30, as is best illustrated in FIGURE 8. The clip applicator 70 is then advanced, which causes the two halves of the body of the retractor 35a, 35b to separate, as shown in FIGURE 7. As the two halves 35a, 35b separate, the patient's tissue is displaced laterally, allowing better access to the puncture site 25 in the femoral artery 10 below the overlying tissues. The clip applicator 70 is advanced through the retractor 30 until the stop on the applicator 85 contacts the proximal end of the retractor 39. At this time, the balloon on the guidewire 24 or catheter is deflated, and the catheter and/or guidewire 20 is removed from the patient. The surgical clips located at the distal tip of the clip applicator 75 are applied to the puncture wound 25, preferably using the method well known to those of ordinary skill in the art. Once the femoral artery puncture wound 25 is closed, the clip applicator 70 and retractor 30 are removed from the patient.

First Alternate Method

Referring now to FIGURES 9-16, a method of using the alternate embodiment of the retractor 100 in conjunction with the dilator 150 and surgical clip applicator assembly 130 to localize and close the femoral artery puncture wound is now described. As

described above, following completion of the angioplasty or angiography, the catheter used during the procedure is removed from the patient's body, leaving only the guidewire threaded into the femoral artery. If desired, before the retractor-dilator assembly 101 (FIGURE 13) is used, a standard dilator of a smaller diameter than that 150 incorporated into the retractor-dilator assembly 101 can be fed onto the proximal end of the guidewire and advanced down the guidewire and into the artery. This preliminary step dilates the overlying tissue if necessary, making it easier to subsequently pass the larger retractor-dilator assembly 101 through the surrounding tissue.

If the tissue has been dilated as above, the smaller bore standard dilator is first removed. The proximal end of the guidewire 144 is first inserted into the distal channel 160 (FIGURE 11) of the dilator 150. The dilator 150 has been previously inserted through the internal channel of the retractor 100, and the retractor 100 advanced over the dilator 150 until the distal tip 112 comes to rest in the notch 152 on the distal tip of the dilator 150. The Y-connector 156 is then attached to the proximal end of the dilator 150 and a syringe 158 attached to one of the ports of the connector 156. The retractor-dilator assembly 101 is then advanced over the guidewire 144 into the patient's body.

While the retractor-dilator assembly 101 is advanced into the patient's body, suction is continuously applied via the syringe 158 or other means of negative pressure (FIGURE 13) to the dilator 150. At the moment the indicator holes 154 enter the lumen of the femoral artery, blood is aspirated into the syringe 158, indicating that the dilator 150 has been inserted through the puncture site into the femoral artery. Thus, the distal tip of the retractor 112, still buried within the notch 152 in the dilator 150, is located just proximal or outside the artery wall at the site of the puncture wound and the indicator holes 154 in the dilator 150 are located just distal or inside the artery lumen.

Alternatively, the dilator 150 includes a pressure sensor (not shown) such as a fiber optic pressure sensor, near its distal tip. The sensor is preferably mounted to the outside wall of the dilator 150. In a preferred embodiment, a transducer-tipped pressure monitoring catheter, such as the Camino Catheter available from Camino Laboratories, San Diego, CA, is used. The pressure sensor, mounted on the outside of the dilator 150, is inserted over the guidewire 144 and into the femoral artery. The pressure sensor, in conjunction with a pressure monitoring system, will indicate an increase in pressure when it is inserted into the femoral artery. At that point, the advancement of the retractor 100 is

stopped, such that the distal tip of the retractor 112 is located just proximal the artery wall 10 at the site of the puncture wound. This allows the physician to properly locate the site of the femoral artery puncture wound in the patient.

5 Once the dilator 150 and retractor 100 are in proper position, the cap 104 is removed from the retractor 100 and the two halves 102a, 102b of the retractor body are separated slightly (FIGURE 10) by loosening the set screws 120a, 120b and sliding the two halves 102a, 102b of the retractor laterally away from one another. This causes the distal tips 112 of two halves 102a, 102b to emerge from the notch 152 in the dilator 150 (FIGURE 11) and straddle the puncture site. The set screws 120a, 120b, are then tightened
10 to hold the two halves 102a, 102b of the retractor 100 in this separated position. While pressing the retractor 100 down against the outer wall of the femoral artery, the dilator 150 is withdrawn, leaving only the retractor 100 and the guidewire 144 in position at the site of the puncture wound in the artery.

To close the wound, the retractor 100 must be retracted far enough to allow the surgical clip applicator assembly 130 to access the puncture site. Upon loosening the set
15 screws 120a, 120b, the two halves 102a, 102b of the retractor are further separated by applying pressure on the retractor pin handle 116c (FIGURES 9-10). When sufficiently retracted, the set screws 120a, 120b on the retractor assembly 100 are tightened to maintain the proper distance between the retractor halves. If necessary, a separate retractor, having
20 a thickness suited for sliding within the grooves 126 in each half 102a, 102b of the retractor body, and a width equal to that of the winged guide plate 138 (FIGURE 14) of the surgical clip applicator guide assembly 134, can be used to open the retractor body to the proper distance.

Second Alternate Method

25 In an alternate embodiment illustrated in FIGURE 17, the modified dilator 150 having a double-sleeved inflatable balloon 170 removably attached to the distal end of the dilator 151, just proximal to the indicator hole 154, is used. The balloon dilator apparatus 175 is inserted over the guidewire 144 into the patient's body. As described above, as the balloon-dilator apparatus 175 is advanced, negative pressure is applied to the system via
30 the syringe or other source. The advance of the balloon-dilator apparatus 175 is stopped as soon as blood is aspirated. The double-sleeved balloon 170 is then inflated to form a

tunnel 176 between the femoral artery puncture wound and the surface of the patient's body, as illustrated in FIGURE 18.

5 The double-sleeved balloon 170 advantageously prevents the femoral artery closure retractor 100 from entering the femoral artery 10 and damaging it. Should the deflated balloon 170 be advanced into the femoral artery 10, the process of inflating the balloon 170 will pull the balloon 170 out of the artery 10, thereby safely creating a tunnel 176 used to access the artery 10.

The balloon 170 is preferably angled at its distal end 172 to allow the balloon 170 to "fit" the femoral artery 10, as shown in FIGURES 17-19.

10 Once the balloon 170 is inflated (FIGURE 18) the retractor 100 is advanced between the two sleeves of the balloon 170, until the distal tip of the retractor 112 reaches the distal end of the double sleeved balloon 170. Once the retractor 100 is positioned between the two sleeves of the balloon 170, the two halves of the retractor 102a, 102b are moved laterally away from one another, as described above. The inner sleeve 178 and the
15 dilator 150 are removed from the patient, leaving the separated retractor 100 and the outer sleeve 180 of the balloon 170 in the patient. The dilator 150 and the inner sleeve 178 are removed from the patient along the guidewire 144.

The retractor 100 and the outer sleeve of the balloon 180 form an access tunnel 182 between the femoral artery puncture wound and the surface of the patient's body, as
20 illustrated in FIGURE 20. This tunnel 182 allows for the introduction of the wound closure device to seal the femoral artery puncture wound.

At this point, with the retractor providing access to the femoral artery, the proximal end of the guidewire 144 is inserted into the guidetube 136 on the surgical clip applicator assembly 130 and the wings on the guide plate are fitted within the grooves 126 of the
25 opened retractor body 102 (FIGURES 14-16). The clip applicator assembly 130 can now be advanced toward the puncture wound, sliding within the grooves 126 in the retractor body 102, guided by the guidewire 144 passing through the guidetube 136 at the distal tip of the surgical clip applicator assembly 130. When the distal tip of the surgical clip applicator 130 has reached the outer wall of the femoral artery 10, at the site of the
30 puncture wound, the surgeon withdraws the guidewire 144 from the patient's body and immediately deploys a surgical clip. A second clip can then be deployed a millimeter or two away from the first clip in order to ensure that the wound is closed.

In a preferred embodiment, just prior to closure of the puncture site, the flexible guidewire 144 used during the primary procedure is replaced with a commercially available guidewire that can become rigid at its distal end, forming a hook. The hooked distal end can be pulled back, "hooking" the puncture wound in the artery. As the guidewire is pulled back further, the puncture wound is stretched into a linear slit, making it more amenable to closure by surgical clips.

Third Alternate Method

Referring now to FIGURES 21-27, a method of using the alternate embodiment of the retractor 200 in conjunction with the dilator 220 and surgical clip applicator assembly 250 to localize and close the femoral artery puncture wound is now described. As described above, following completion of the angioplasty or angiography, the catheter used during the procedure is removed from the patient's body, leaving only the guidewire 240 threaded into the femoral artery 10.

The proximal end of the guidewire 240 is first inserted into the distal lumen 236 (FIGURE 26) of the dilator 220. The dilator 220 is advanced over the guidewire 240 into the patient's body. As described above, as the balloon-dilator apparatus 250 is advanced, negative pressure is applied to the system via the syringe or other source connected at the proximal end of the dilator 225. The advance of the dilator 220 is stopped as soon as blood is aspirated through the indicator hole 228, thus indicating that the distal end of the dilator 226 is positioned within the femoral artery 10. The distal balloon 224 and the double-sleeved balloon 222 are then inflated to anchor the dilator 220 in place and to form a tunnel between the femoral artery puncture wound and the surface of the patient's body.

Once the balloons 222, 224 are inflated, the retractor 200 is advanced between the two sleeves 229, 230 of the double sleeved balloon 222. As illustrated in FIGURE 24, the inner sleeve 230 of the double sleeved balloon 222 can be in an "I" shape, which provides more space between the two sleeves to insert the two halves 202a, 202b of the reactor 200. The retractor 200 is advanced between the two sleeves 229, 230, as described above, until the distal tip of the retractor 204 is positioned just proximal to the puncture wound in the femoral artery 10.

Once the retractor 200 is positioned between the two sleeves of the balloon 229, 230, the two halves of the retractor 202a, 202b are moved laterally away from one another. This is done by loosening the set screws 214a, 214b, and sliding one half of the retractor

body 202b away from the other half 202a on the pins 212a 212b. The inner sleeve 230 of the double-sleeved balloon 222 and the dilator 220 are removed from the patient along the guidewire 240, leaving the separated retractor 200 and the outer sleeve 229 of the balloon 222 in the patient. The retractor 200 and the outer sleeve of the balloon 229 form an access tunnel between the femoral artery puncture wound and the surface of the patient's body. This tunnel allows for the introduction of the wound closure device to seal the femoral artery puncture wound.

At this point, with the retractor 200 and outer sleeve of the balloon 229 providing access to the femoral artery 10, the proximal end of the guidewire 240 is inserted into the distal end 262 of the indicator tube 260 which is mounted on the surgical clip applicator 252. As described above, the distal end 262 of the indicator tube 260 having an indicator hole 264 in it is positioned so that the indicator hole 264 extends past the distal end 256 of the clip applicator 252. The indicator tube 260 and the clip applicator 252 are advanced over the guidewire 240 while aspiration pressure is applied to the proximal end of the indicator tube 260. As soon as blood is aspirated through the indicator hole 264, the advancement of the indicator tube 260 and clip applicator 256 is stopped. At this point, the distal end of the surgical clip applicator 256 is positioned at the site of the puncture wound in the femoral artery 10. Surgical clips are then applied to seal the wound.

Preferably, the distal end of the indicator tube 262 is curved or hooked. The hooked distal end is used to hook the puncture wound in the artery, bringing the edges of the wound together to facilitate application of the clip. Using the hooked distal end 262 of the indicator tube 260, the puncture wound is stretched into a linear slit, making it more amenable to closure by surgical clips.

Fourth Alternate Method

Referring now to FIGURES 28-31, still another method of closing a wound in the femoral artery of a patient will be described. Here again, the femoral artery is first punctured with a hollow needle and a guidewire 350 is inserted therethrough. A proximal portion of the guidewire 351 remains outside the patient's body. After the distal end of the guidewire 353 is in position within the femoral artery, the hollow needle is removed. Diagnostic and/or therapeutic procedures are then carried out, using the guidewire 350 to guide the insertion of the other medical instruments into the vasculature of the patient.

Following completion of the therapeutic or diagnostic procedure, the devices used during the procedure are removed. The guidewire 350 remains in place in the patient's vasculature. When the physician desires to close the wound in the artery, he or she first mounts the retractor 300 on the distal end of the dual-lumen catheter 340. This is done by loosening the screw 322 on one of the handles 316b, and moving the handles 316a, 316b away from one another to separate the two halves of the retracting portion 308, and the two parts of the retracting portion 308a, 308b are positioned around the dual-lumen catheter 340. The dual lumen catheter 340 fits within the semi-circular channel or grooves 312 formed in the inner surface of the retracting portion 308 of the retractor 300. The two halves of the retracting portion 308a, 308b are brought together using the handles 316a, 316b to surround the catheter 340. The retracting portion 308 is positioned on the catheter 340 just proximal to the raised portion of the catheter 354, so the distal tip of the retracting portion 310 is located just proximal to the indicator hole 352. Preferably, the distal tip of the retracting portion 308 will be approximately 0.5 mm behind the indicator hole 352 (see FIGURE 31). Once in position, the screw 322 is tightened on the loop 320 to lock the two parts of the retracting portion 308a, 308b in position on the catheter 340.

Once the retractor 300 is properly positioned on the dual-lumen catheter 340, the physician inserts the proximal end 351 of the guidewire 350 into the distal end of the inner lumen 342 in the dual-lumen catheter 340. The dual-lumen catheter 340 and retractor 300 are advanced over the guidewire 350 and into the patient. As the catheter 340 and retractor 300 are advanced, negative pressure is applied to the outer lumen of the catheter, for example, through use of a syringe 360 attached to the proximal end of the outer lumen 358. Once the indicator hole 352 is advanced to a position inside the artery, blood will be drawn through the indicator hole 352 and will become visible in the outer lumen of the catheter 340 and the syringe 360. At this point, advancement of the catheter 340 and retractor 300 are stopped, as the catheter 340 and retractor 300 are properly positioned in the patient.

Once properly positioned at the site of the puncture wound, the two halves of the retracting portion 308a, 308b are separated slightly, using the handles 316a, 316b at the proximal end 304 of the retractor 300. To separate the retracting portions 308a, 308b, the screw 322 is loosened, and the handles 316a, 316b manipulated into the desired position.

The screw 322 is then tightened down upon the loop 320, prohibiting further movement of the handles 316a, 316b, and the corresponding retracting portions 308a, 308b.

At this point, the surrounding tissues have been displaced, forming an access path to the puncture wound, and the puncture wound may be visible. The dual-lumen catheter 340 is removed from the patient by withdrawing it over the guidewire 350. The guidewire 350 is left in place, and the wound closure device, such as a clip applicator, is inserted over the guidewire 350 to the site of the wound. Clips, such as those made of titanium or a biodegradable material, are preferably applied to the wound, as the guidewire 350 is removed. If necessary, the artery is compressed to stop the flow of blood out of the puncture wound during the closing of the wound. The closing device is removed when the physician is confident that the wound is closed, and the retractor 300 is removed from the patient.

Alternatively, a separate inner catheter 360 is used in the system of the present invention. In this embodiment, once the retractor 300 and dual-lumen catheter 340 are in place, and the retracting portion 308 is in an open position, the dual-lumen catheter 340 is left in place, and the guidewire 350 is withdrawn from the patient through the inner lumen 342. An inner catheter 360 having an inflatable balloon 362 at its distal end is inserted through the inner lumen 342 and into the patient. Once the distal balloon 362 is advanced past the distal tip 346 of the dual-lumen catheter 340, the balloon 362 is inflated. The dual-lumen catheter 340 is removed from the patient, leaving the inner catheter 360 in place.

To properly position the balloon inside the patient's artery, the physician can measure the distance from the distal tip of the dual-lumen catheter 346 to just outside the patient's body when the catheter 340 is properly positioned. The physician then inserts the inner catheter 360 just slightly more than that distance, to ensure that the distal balloon 362 is within the artery. The physician then pulls the inner catheter 360 in a proximal direction until resistance is felt. This will place the balloon 362 at the site of the puncture wound. The balloon 362 is properly positioned just inside the artery of the patient. The balloon 362 helps to stop the flow of blood out of the puncture wound. The inner catheter 360 is used as a guide for the clip applicator or other closing device used to close the wound. The closing device is advanced until it contacts the inflated balloon 362. As the wound is closed, the balloon 362 is slowly deflated, and the inner catheter 360 is removed from the

patient. Finally, once the physician is confident that the wound is closed, the retractor 300 is removed from the patient.

This method of closing a wound in the femoral artery of a patient can also be performed using the retractor 600 described in Figures 48-50 in place of the retractor 300 discussed above. To mount the retractor 600 on the distal end of the dual lumen catheter 340, the clinician squeezes the release member arm 626 so that the head stop 664 is clear of the stop member teeth 622. The handles are also squeezed together in order to separate the two halves 608a, 608b of the retracting portion so that the retracting portion halves may be positioned around the dual lumen catheter 340. As above, the catheter fits within the semi-circular channel or grooves 612 of the retracting portion halves 608a, 608b. When the retracting portion 608 is positioned on the catheter 340 just proximal to a raised portion of the catheter so that the distal tip 610 of the retracting portion 608 is located just proximal to the indicator hole 352, the clinician releases the squeezing hold on the handles 616a, 616b. Thus, the spring 640 urges the retracting halves 608a, 608b to close around the catheter. The force F' exerted by the spring 640 on the handles 616a, 616b operates to retain the catheter 340 securely between the retractor halves 602a, 602b.

The dual lumen catheter 340 and retractor 600 are next advanced over the guidewire, preferably in the same manner described above, until the assembly is properly positioned at the vascular puncture wound. The retracting portions 608a, 608b are next separated in order to displace the surrounding tissue. To separate retracting portions, the clinician squeezes the handles 616a, 616b. During the squeezing operation, the head stop 634 ratchets over the stop member teeth 622. Thus, when the desired open position is reached, the clinician need only release the handles 616a, 616b and the stop 634 will engage the teeth 622 in order to hold the retracting halves 608a, 608b in the chosen open position. With the surrounding tissues displaced, forming an access path to the vascular puncture wound, the vascular wound can be closed by using a suitable apparatus or method.

To remove the retractor 600 from the patient, the retracting portions 608a, 608b are first brought together into the closed position by the clinician squeezing the release arm 626 toward the handle 616a. The stop 634 is thus disengaged from the stop arm teeth 622 and the spring 640 urges the handles 616a, 616b apart. Thus, the retracting portions 608a,

608b are drawn together into the closed position. The retractor 600 is then easily removed from the patient.

Alternate Apparatus for Vessel Closure

Referring now to FIG. 32, there is illustrated another apparatus contemplated for closure of an opening in a vascular organ, e.g., blood vessel subsequent to an angiography, angioplasty procedure, etc. Apparatus 400 includes vascular closure instrument 402 and a vacuum source 404 (shown schematically in FIG. 32) which is connectable to the vascular closure instrument. Vacuum source 404 may be any vacuum generator suitable for the surgical procedure to be described.

With references to FIGS. 32-34, vascular closure instrument 402 includes handle 406, and an elongated portion 408 extending distally from the handle 406 and defining longitudinal axis 408a. Handle 406 is generally cylindrical in configuration, however, other designs are contemplated as well. Vascular closure instrument 402 includes a longitudinal lumen 410 extending the length of the instrument 402 through handle 406 and elongated portion 408 and terminating in distal axial opening 412. Longitudinal or vacuum lumen 410 conveys the vacuum provided by vacuum source 404. FIG. 34 illustrates suitable tubing "t" connecting vacuum source 404 and closure instrument 402.

Vascular closure instrument 402 further includes a pair of surgical clips 414 supported at the distal end of elongated portion 408. Surgical clips 414 may be any conventional surgical clip fabricated from a suitable biocompatible material including absorbable and non-absorbable materials. Clips 414 are characterized by having backspan 414a and clip legs 414b (FIG. 35). Clip legs 414b are adapted to move or pivot inwardly to a closed or formed condition thereof in response to inward force applied to the clip legs 414b.

Surgical clips 414 are releasably mounted to elongated portion 408. In one arrangement, elongated portion 408 includes first and second pairs of longitudinal grooves 416 formed in the distal end of the elongated portion 408. Longitudinal grooves 416 extend in a longitudinal direction and terminate in transverse grooves 418 (FIG. 33) adjacent the proximal end of the longitudinal grooves 416. Transverse grooves 418 receive surgical clips 414, more specifically, backspans 414a of the surgical clips 414 to mount the surgical clips 414 in a releasable manner. Transverse grooves 418 are preferably dimensioned such that a frictional relationship is established to further facilitate

mounting of the clips 414 to the instrument 402. Each surgical clip 414 is loaded by positioning backspan 414a within longitudinal groove 416, advancing the clips 414 in a proximal direction adjacent transverse grooves 418 and manipulating the backspans 414a to be received within the transverse grooves 418. Other means for mounting surgical clips 414 to elongated portion 408 may be readily appreciated by one skilled in the art.

With continued reference to FIGS. 32-35, vascular closure instrument 402 further includes clip forming mechanism, generally identified as reference numeral 420, mounted to elongated portion 408 of the instrument. In the preferred embodiment, clip forming mechanism 420 includes a pair of manually operable levers 422 mounted to the outer surface of elongated portion 408 in diametrically opposed relation. Manually operable levers 422 are mounted at their proximal end portions via mounting pins 424 whereby the distal end portions of the manually operable levers 422 may move in a radially direction, i.e., toward each other, to form surgical clips 414.

As best depicted in FIGS. 32-33, elongated portion 408 defines a non-circular or oval cross-section having a major cross-sectional dimension "a" (FIG. 33). Such configuration advantageously facilitates closure of an elongated incision formed in the blood vessel. In particular, an incision made in the blood vessel in connection with an angioplasty or angiography procedure is preferably elongated in the direction of the axis of the blood vessel. Accordingly, by applying vascular closure instrument 402 to the opening with the major axis "a" extending in the general direction of the opening, the surgeon is assured that the vessel opening is confined within the perimeter of the elongated portion 408. In addition, the oval cross-section corresponds to the internal dimension of the aforescribed retractors, including retractor 100 and retractor 300, when in an open condition, thereby facilitating use of the wound closure instrument 402 with these instruments, e.g., positioning of the closure instrument 402 within the open retractor and advancing the instrument 402 therewithin. For a typical puncture wound having a diameter or length of about 1mm, the elongated portion 408 preferably has a major axis "a" of about 3-5mm and most preferably about 4mm.

Elongated portion 408 of vascular closure instrument may further include a wrap 425, e.g., shrink wrapping, or the like shown cut-away in FIG. 32. Wrap 425 preferably extends to the distal end of elongated portion 408 of vascular closure instrument 402 to at

least partially enclose longitudinal grooves 416 and transverse grooves 418 to preserve the integrity of the vacuum within vacuum lumen 408.

The operation of vascular closure instrument in conjunction with closing an opening in a blood vessel wall will now be discussed. Access to the puncture site is preferably achieved with the guidewire, dilator, retractor instruments discussed above. With reference to FIGS. 34-35, vascular closure instrument 402 is positioned adjacent the opening "o" in vessel "v" with the major axis of the oval extending in the general direction of the axis "a" of the blood vessel "v." By virtue of the oval cross-section, the entire opening or incision "o" is confined within the perimeter of the elongated portion. Vacuum source 402 is actuated which thereby creates a vacuum within vacuum lumen 410. Due to the effect of the vacuum forces, shown in FIG. 34 by the directional arrows "s," the vessel edge portions "e" defining the vessel opening "o" are at least partially drawn into distal axial opening 412 of elongated portion 408 to assume an everted condition as shown. With reference now to FIGS. 36-37, with the vessel edge portions "e" everted and in position to be engaged by clip legs 414b of surgical clips 414, manually operable levers 422 are moved radially inwardly in the direction of directional arrows "f" by a force exerted by the user to pivot clip legs 414b and form surgical clips 414. In the formed condition, clip legs 414b engage the vessel edge portions "e" to generally approximate the edges "e" to close the opening. Thereafter, surgical clips 414 are released from their mounting to elongated portion 408 by manipulating the vascular closure instrument 402 to align clip backspan 414a with longitudinal grooves 416 thereby permitting the instrument to be withdrawn leaving the surgical clips 414 in place.

FIGS. 38-39 illustrate an alternate embodiment of the vascular closure instrument. In accordance with this embodiment, a side opening port 430 (shown in phantom) is provided in the elongated portion 408 to permit passage of the proximal end of a guidewire "g." When used with the guidewire "g" in place within the vessel opening, the guidewire "g" is introduced within distal opening 412 and manipulated to the side opening port 430 and passed therethrough. Thereafter, the vascular closure instrument is advanced along the guidewire to the opening site. As best depicted in FIG. 39, the guidewire "g" is preferably positioned adjacent the periphery of the elongated portion 408 so as to not interfere with the clip forming process. More preferably, the guidewire "g" is placed about $\frac{1}{4}$ - $\frac{1}{2}$ of the length of the major axis "a" from the periphery of the axial opening 412 so as not to

interfere with the everted vessel edges. Most preferably, the guidewire "g" is positioned about 1/3 of the length of the major axis "a" into the opening 412. Also, a separate guidewire lumen or tube may be incorporated in elongated portion 408 to receive the guidewire "g." If in the form of a tube, such tube may be attached to the inner wall of elongated portion 408 and extend to side opening port 430.

Locating a Tissue Opening

Referring to FIGURES 40-41, an apparatus and method for locating a vessel opening is described. In FIGURE 40, the locator apparatus 500, which is in communication with a vacuum or source of suction (not shown), has not completely isolated the vessel opening 25. Thus, the locator apparatus 500 draws both blood and other bodily fluid with its suction. In FIGURE 41, the locator apparatus 500 has completely isolated the vessel opening 25 and now only draws blood through its lumen. The blood is transferred to the proximal end of the apparatus 500 or to some other location external of the body to provide a visual indication that the apparatus 500 has located the opening 25. In this position, the locator apparatus 500 can hold onto the vessel 10 with its suction and maintain the apparatus 500 over the opening.

Referring to FIGURES 42a and 42b, an alternate locator apparatus 500 is shown with an external guidewire lumen 507. An internal guidewire lumen 508 is shown in FIGURE 42b.

Referring to FIGURE 43, a preferred locator apparatus 500 is shown with external medical delivery devices 508a and 508b, which can deliver medical treatment to the area surrounding the vessel opening 25. Also, internal medical delivery devices 509a and 509b can deliver medical treatment to the vessel opening 25 or to the vessel 10 itself. The medical treatment can be therapeutic, e.g. radiation or drug delivery.

Referring to FIGURE 47, a preferred apparatus for locating a vessel opening is illustrated. Suction apparatus 500 includes a vacuum source 505 (shown schematically). The suction apparatus 500 may also be connected to a closure device 504 (shown schematically) via attachment ports 506. Vacuum source 505 may be any vacuum generator suitable for the surgical procedure to be described. The apparatus 500 may also include closure devices 504 (shown schematically), which may also be inside the apparatus 500.

Referring to FIGURES 44-47, a method of locating a vessel opening is illustrated. In particular, a guidewire "g" is strung through the vessel opening as described previously. The suction apparatus 500 has the guidewire "g" strung through it by the guidewire guide 503. As the distal axial opening 502 nears the vessel opening 25, the vacuum forces of the suction apparatus 500 draws both blood and clear bodily fluid from the area surrounding the vessel opening 25. When the distal axial opening 502 completely covers the vessel opening 25, the suction apparatus 500 has isolated the vessel opening 25. At this point, the vacuum forces of the suction apparatus 500 only draws blood. Also, once the vessel opening 25 has been isolated, the vacuum forces of the suction device 500 cause the edges of the vessel opening 25 to evert 26.

Once the vessel opening 25 has been isolated, a closure device 504 attached to the suction device 500 can be used to close the vessel opening 25.

The present invention can also be used with surgical staples or sutures. After the retractor is inserted into the patient's body and positioned at the puncture site as described above, the two halves of the retractor are separated, laterally displacing the tissues surrounding the puncture site. The retractor acts much like a dilator, gradually increasing the displacement of the overlying tissues, until the puncture wound is visible to the physician. The wound can then be closed using any acceptable means for wound closure, including surgical staples and sutures.

Although certain embodiments and examples have been used to illustrate and describe the present invention, it is intended that the scope of the invention not be limited to the specific embodiments set forth herein. The scope of the invention is to be defined by the claims which follow.